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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,458	08/11/2000	Yumi Matsuzaki	195675US0	8810
22850	7590	12/17/2003	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 12/17/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/636,458	MATSUZAKI ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

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| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input checked="" type="checkbox"/> Other: <u>Attachment on Deposits of Biological Materials</u></p> |
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Detailed Action

The Abstract needs to be revised in order to reflect the elected subject matter.

A substitute specification (absent the claims) in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

The above requirements are repeated. Applicants have not responded to these requirements in their response filed 9/15/03 and therefore said requirements are maintained.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-17 and 29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims recite plasmids (or a polynucleotide) comprising a gene encoding a protein(s) having Rep activity wherein said Rep proteins have a degree of homology to SEQ ID NO:4. The recited plasmids can be isolated from microorganisms such as *Corynebacteria*. The plasmids and polynucleotides are not recited as being isolated or recombinant and hence read on naturally occurring plasmids (a product of nature) with the recited properties.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 29 (and dependent claims 10, 14-21, 24-29) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim plasmids and polynucleotides comprising an amino acid sequence that "...**is at least** (emphasis added) 81.91% homologous to the amino acid sequence of SEQ ID NO:4". The specification provides support only for a single embodiment (species) of a Rep protein which is 81.91% homologous to SEQ ID NO:4 and does not provide support for claims reading on a genus of Rep proteins having **at least** 81.91% homology to SEQ ID NO:4. This is a NEW MATTER rejection.

Claims 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants claim plasmids isolated from four different *Corynebacterium thermoaminogenes* strains (AJ12308, AJ12310, AJ12340 and AJ12309). These strains

appear to have been previously deposited by others and it is unclear (given the lack of a specification written in idiomatic English) if applicants themselves have re-deposited them. Since these strains are essential for practicing the claimed invention and given that neither applicants nor the prior art have provided a protocol whereby the skilled artisan could reliably reproduce said strains, applicants must themselves deposit these strains and satisfy the deposit requirements under 37 CFR 1.801-1.809 (See Attachment on Deposits of Biological Materials).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 11-13, 29 (and dependent claims) are vague in that applicants recite a plasmid comprising a gene having Rep protein activity and comprising an amino acid sequence homologous to SEQ ID NO:4. It is unclear how a plasmid (a nucleic acid molecule) can comprise an amino acid sequence.

Claims 18 and 21-24 are vague in that there is no antecedent basis for the term "the *Corynebacterium thermoaminogenes*" in the claims from which they depend.

Claims 18, 21-28 (and dependent claims) are vague in that said claims recite a method of isolating plasmids but the method claims do not recite any step(s) which actually results in isolation of the plasmid. Since the methods do not contain a step(s)

which recapitulates the preamble of the claim, it is unclear what other steps are involved in the recited methods. Therefore, the metes and bounds of the claims are unclear.

Claim 19 is vague in that applicants recite "gathering plasmid fractions" by an alkali method. It is unclear where the plasmid fractions came from since the only step previously recited in the method was culturing the *C. thermoaminogenes* in culture medium. It appears that there are missing steps in the recited method, i.e. lysing the cells to obtain the plasmids, separating the DNA plasmids into fractions, etc.

No Claims are allowed.

Any rejections not repeated in this Office Action are withdrawn.

Applicants arguments presented in the response filed 9/15/03 have been considered. The arguments essentially deal with written description and enablement for the composition claims and are persuasive as no written description or enablement rejections are made in this Office Action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. After January 14, 2004, the examiner can be reached at (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
December 10, 2003



DAVID GUZO
PRIMARY EXAMINER